

## Remarks

The Examiner rejected claims 1-6 and 8-13 under 35 U.S.C. §112, second paragraph, as being indefinite, with specific references to claims 1, 4, 9, and 12. In response, the Applicant has amended claims 1, 4, 9, and 12 to address each of the issues raised by the Examiner.

The Examiner rejected claims 1-3 under 35 U.S.C. §102(b) as being anticipated by Krakovsky et al. Specifically, the Examiner stated that “Krakovsky shows the pulse generator, 46, battery, 40, and lead containing electrode, 48, and is capable of meeting the functional use recitations presented in the claim since it is an implantable device with an implantable lead and electrode. In response, the Applicant has amended claims 1 and 12 to more specifically distinguish the claims.

The Examiner also rejected claims 1-3, 5, and 10 under 35 U.S.C. §102(b) as being anticipated by Meloy et al, stating that “Meloy is capable of meeting the functional use recitations presented in the claims, such as being implanted in certain areas, since the lead, electrode, and system are implantable. The Examiner also rejected claims 1-3 under 35 U.S.C. §102(b) as being anticipated by Ardito et al, stating that “Ardito is capable of meeting the functional use recitations presenting in the claims, such as being implanted in certain areas, since the lead, electrode, and system are implantable. While reserving the right to further distinguish claim 1 from Meloy and Ardito, as noted, the Applicant has amended claim 1 that in any event is distinguishable from Meloy and Ardito.

The Examiner further rejected claims 4, 5, and 10 under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Krakovsky.

Specifically, the Examiner states that “Krakovsky use a lithium battery LBSAR 5 which is a ‘high’ impedance battery...[and that] Krakovsky uses 2,5-5 volt pulses at a frequency of 2 Hz which is about the claimed ‘about 10 Hz’ high frequency pulses of claims 5 and 10.”

Alternatively, the Examiner states that “Krakovsky discloses the claimed invention using 2.5-5 volt pulses and that the pulse parameters (height, frequency, etc) can be changed for each individual patient by testing (column 3) but does not disclose expressly the high impedance battery and the use of high frequency pulses of about 10-40 Hz.” The Examiner further concludes that it would have been obvious to modify Krakovsky’s generator with the high impedance battery “because the Applicant has not discloses that the high impedance battery provides an advantage, is used for a particular purpose, or solves a stated problem.” The Examiner states that “one of ordinary skill...would have expected Applicant’s invention to perform equally well with Krakovsky’s lithium battery because it provides a long lifetime of 5-8 years to operate the pulse generator.” The Examiner further states that “Krakovsky provides a clear suggestion that the pulse height and frequency can be modified to determine the appropriate stimulation parameters based on the particular patient and place of stimulation...[and that] the determination of the most appropriate pulse height and frequency, such as about 10-40 Hz and 1 to 5,5 V, by routine experimentation would...be prima facie obvious on one...in the medical art.”

In response to the Examiner’s 112 rejection of claim 4, the Applicant amended claim 4 to more specifically claim the high impedance battery of claim 4. As more specifically claimed, the Applicant believes that claim 4 is distinguishable from and nonobvious in view of Krakovsky.

The Examiner also rejected claims 6, 9, and 11-13 under 35 U.S.C. §103(a) as being unpatentable over Krakovsky. Specifically, the Examiner stated that “Krakovsky discloses the claimed invention using 2.5-5 Volt pulses, that the pulse parameters...can be changed for each individual patient by testing...and the use of other electrodes for connecting to the nerves/muscles.” However, the Examiner noted that Krakovsky does not disclose low amplitude, high frequency pulses of 10-40 Hz and 1 to 5.5 Volts (claim 13), the lead with an outside diameter of 2 mm or less with extension cable/lead (claim 6), the power source and generator housed in a biocompatible titanium shell (claims 9 and 12) and the tip electrode comprised of an indifferent material (claims 11 and 12). Without citing any references, the Examiner concludes that it would have been obvious to modify Krakovsky to include all these elements because “it was known in the art that implantable devices use” these elements. As noted, the Applicant has amended independent claims 1 and 12 which now more specifically claim the invention.

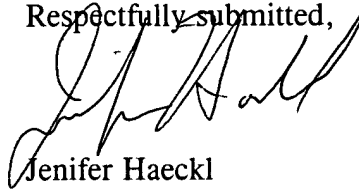
The Examiner also stated that claim 8 would be allowable is rewritten to overcome Section 112 rejections and to include all the limitations of the base claim and any intervening claims. In response, the Applicant has amended claim 1 to include the limitations of claim 8 and to address the Section 112 rejection of claim 1, and therefore has canceled claim 8.

Each of the Examiner's rejections has been addressed. Accordingly, it is respectfully submitted that the application is in condition for allowance. Early and favorable action is requested.

If for any reason this Response is found to be incomplete, or if at any time it appears that a telephone conference with counsel would help advance prosecution, please telephone the

undersigned in Worcester, Massachusetts at (508) 791-8500.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Jenifer Haeckl", written over the printed name.

Jenifer Haeckl

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